(21)

Supreme Court, U.S.
FILED
SEP 10 1999
OFFICE OF THE CLERK

No. 98-1152

IN THE
Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, *et al.*,
Petitioners,

v.

BROWN AND WILLIAMSON TOBACCO CORP., *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

APPENDIX TO BRIEF FOR RESPONDENTS UNITED STATES TOBACCO COMPANY, *ET AL.*

LARRY B. SITTON
Counsel of Record
SMITH HELMS MULLISS & MOORE, L.L.P.
300 North Greene Street
Suite 1400
Greensboro, NC 27420
(336) 378-5200
Counsel for United States Tobacco Company, Conwood Company, L.P., National Tobacco Company, L.P., The Pinkerton Tobacco Company, and Swisher International, Inc.

WILSON - EPES PRINTING CO., INC. - 789-0096 - WASHINGTON, D.C. 20001

BEST AVAILABLE COPY

63pp

JOHN R. JORDAN, JR.
JORDAN, PRICE, WALL, GRAY,
JONES & CARLTON
225 Hillsborough Street
Raleigh, NC 27603
Counsel for
North Carolina Tobacco
Distributors Committee, Inc.

NORWOOD ROBINSON
MICHAEL L. ROBINSON
ROBINSON & LAWING, L.L.P.
370 Knollwood Street
Suite 600
Winston-Salem, NC 27103
Counsel for
Central Carolina Grocers, Inc.,
and J.T. Davenport, Inc.

DANIEL A. KRACOV
PATTON BOGGS, L.L.P.
2550 M Street, N.W.
Washington, D.C. 20037
Counsel for
Conwood Company, L.P.,
National Tobacco Company,
L.P., The Pinkerton Tobacco
Company, and Swisher
International, Inc.

THOMAS SCARLETT
JENNIFER B. DAVIS
HYMAN, PHELPS & MCNAMARA, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, D.C. 20005
Counsel for
United States Tobacco
Company

BEST AVAILABLE COPY

TABLE OF CONTENTS

Public Law 59-384
59th Congress

CHAP. 3915.—An Act For preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That it shall be unlawful for any person to manufacture within any Territory or the District of Columbia any article of food or drug which is adulterated or misbranded, within the meaning of this Act; and any person who shall violate any of the provisions of this section shall be guilty of a misdemeanor, and for each offense shall, upon conviction thereof, be fined not to exceed five hundred dollars or shall be sentenced to one year's imprisonment, or both such fine and imprisonment, in the discretion of the court, and for each subsequent offense and conviction thereof shall be fined not less than one thousand dollars or sentenced to one year's imprisonment, or both such fine and imprisonment, in the discretion of the court.

SEC. 2. That the introduction into any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or from any foreign country, or shipment to any foreign country of any article of food or drugs which is adulterated or misbranded, within the meaning of this Act is hereby prohibited; and any person who shall ship or deliver for shipment from any State or Territory or the District of Columbia to any

other State or Territory or the District of Columbia, or to a foreign country, or who shall receive in any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or foreign country, and having so received, shall deliver, in original unbroken packages, for pay or otherwise, or offer to deliver to any other person, any such article so adulterated or misbranded within the meaning of this Act, or any person who shall sell or offer for sale in the District of Columbia or the Territories of the United States any such adulterated or misbranded foods or drugs, or export or offer to export the same to any foreign country, shall be guilty of a misdemeanor, and for such offense be fined not exceeding two hundred dollars for the first offense, and upon conviction for each subsequent offense not exceeding three hundred dollars or be imprisoned not exceeding one year, or both, in the discretion of the court: *Provided*, That no article shall be deemed misbranded or adulterated within the provisions of this Act when intended for export to any foreign country and prepared or packed according to the specifications or directions of the foreign purchaser when no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which said article is intended to be shipped; but if said article shall be in fact sold or offered for sale for domestic use or consumption, then this proviso shall not exempt said article from the operation of any of the other provisions of this Act.

SEC. 3. That the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce and Labor shall make uniform rules and regulations for carrying out the provisions of this Act, including the collection and examination of specimens of foods and drugs

manufactured or offered for sale in the District of Columbia, or in any Territory of the United States, or which shall be offered for sale in unbroken packages in any State other than that in which they shall have been respectively manufactured or produced, or which shall be received from any foreign country, or intended for shipment to any foreign country, or which may be submitted for examination by the chief health, food, or drug officer of any State, Territory, or the District of Columbia, or at any domestic or foreign port through which such product is offered for interstate commerce, or for export or import between the United States and any foreign port or country.

SEC. 4. That the examinations of specimens of foods and drugs shall be made in the Bureau of Chemistry of the Department of Agriculture, or under the direction and supervision of such Bureau, for the purpose of determining from such examinations whether such articles are adulterated or misbranded within the meaning of this Act; and if it shall appear from any such examination that any of such specimens is adulterated or misbranded within the meaning of this Act, the Secretary of Agriculture shall cause notice thereof to be given to the party from whom such sample was obtained. Any party so notified shall be given an opportunity to be heard, under such rules and regulations as may be prescribed as aforesaid, and if it appears that any of the provisions of this Act have been violated by such party, then the Secretary of Agriculture shall at once certify the facts to the proper United States district attorney, with a copy of the results of the analysis or the examination of such article duly authenticated by the analyst or officer making such examination, under the oath of such officer. After judgment of the court, notice shall be given by publication in such manner as may be prescribed by the rules and regulations aforesaid.

SEC. 5. That it shall be the duty of each district attorney to whom the Secretary of Agriculture shall report any violation of this Act, or to whom any health or food or drug officer or agent of any State, Territory, or the District of Columbia shall present satisfactory evidence of any such violation, to cause appropriate proceedings to be commenced and prosecuted in the proper courts of the United States, without delay, for the enforcement of the penalties as in such case herein provided.

SEC. 6. That the term "drug," as used in this Act, shall include all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals. The term "food," as used herein, shall include all articles used for food, drink, confectionery, or condiment by man or other animals, whether simple, mixed, or compound.

SEC. 7. That for the purposes of this Act an article shall be deemed to be adulterated:

In case of drugs:

First. If, when a drug is sold under or by a name recognized in the United States Pharmacopoeia or National Formulary, it differs from the standard of strength, quality, or purity, as determined by the test laid down in the United States Pharmacopoeia or National Formulary official at the time of investigation: *Provided*, That no drug defined in the United States Pharmacopoeia or National Formulary shall be deemed to be adulterated under this provision if the standard of strength, quality, or purity be plainly stated upon the bottle, box, or other container thereof although the standard may differ from that determined by the test laid down in the United States Pharmacopoeia or National Formulary.

Second. If its strength or purity fall below the professed standard or quality under which it is sold.

In the case of confectionery:

If it contain terra alba, barytes, talc, chrome, yellow, or other mineral substance or poisonous color or flavor or other ingredient deleterious or detrimental to health or any vinous, malt or spirituous liquor or compound or narcotic drug.

In the case of food:

First. If any substance has been mixed and packed with it so as to reduce or lower or injuriously affect its quality or strength.

Second. If any substance has been substituted wholly or in part for the article.

Third. If any valuable constituent of the article has been wholly or in part abstracted.

Fourth. If it be mixed, colored, powdered, coated, or stained in a manner whereby damage or inferiority is concealed.

Fifth. If it contain any added poisonous or other added deleterious ingredient which may render such article injurious to health: *Provided*, That when in the preparation of food products for shipment they are preserved by any external application applied in such manner that the preservative is necessarily removed mechanically, or by maceration in water, or otherwise, and directions for the removal of said preservative shall be printed on the covering or the package, the provisions of this Act shall be construed as applying only when said products are ready for consumption.

Sixth. If it consists in whole or in part of a filthy, decomposed, or putrid animal or vegetable substance, or any portion of an animal unfit for food, whether manufactured or not, or if it is the product of diseased animal, or one that has died otherwise than by slaughter.

SEC. 8. That the term "misbranded," as used herein, shall apply to all drugs, or articles of food, or articles which enter into the composition of food, the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular, and to any food or drug product which is falsely branded as to the State, Territory, or country in which it is manufactured or produced.

That for the purposes of this Act an article shall also be deemed to be misbranded:

In case of drugs:

First. If it be an imitation of or offered for sale under the name of another article.

Second. If the contents of the package as originally put up shall have been removed, in whole or in part, and other contents shall have been placed in such package, or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein.

In the case of food:

First. If it be an imitation of or offered for sale under the distinctive name of another article.

Second. If it be labeled or branded so as to deceive or mislead the purchaser, or purport to be a foreign product when not so, or if the contents of the package as originally put up shall have been removed in whole or in part and other contents shall have been placed in such package, or if it fail to bear a statement on the label of the quantity or proportion of any morphine, opium, cocaine, hereoin, alpha or beta eucane, chloroform, cannibis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any of such substances contained therein.

Third. If in package form, and the contents are stated in terms of weight or measure, they are not plainly and correctly stated on the outside of the package.

Fourth. If the package containing it or its label shall bear any statement, design, or device regarding the ingredients or the substances contained therein, which statement, design, or device shall be false or misleading in any particular: *Provided*, That an article of food which does not contain any added poisonous or deleterious ingredients shall not be deemed to be adulterated or misbranded in the following cases:

First. In the case of mixtures or compounds which may be now or from time to time hereafter known as articles of food, under their own distinctive names, and not an imitation of or offered for sale under the distinctive name of another article, if the name be accompanied on the same label or brand with a statement of the place where said article has been manufactured or produced.

Second. In the case of articles labeled, branded, or tagged so as to plainly indicate that they are compounds, imitations, or blends, and the word "compound," "imitation," or "blend," as the case may be, is plainly stated on the package in which it is offered for sale: *Provided,*

That the term blend as used herein shall be construed to mean a mixture of like substances, not excluding harmless coloring or flavoring ingredients used for the purpose of coloring and flavoring only: *And provided further*, That nothing in this Act shall be construed as requiring or compelling proprietors or manufacturers of proprietary foods which contain no unwholesome added ingredient to disclose their trade formulas, except in so far as the provisions of this Act may require to secure freedom from adulteration or misbranding.

SEC. 9. That no dealer shall be prosecuted under the provisions of this Act when he can establish a guaranty signed by the wholesaler, jobber, manufacturer, or other party residing in the United States, from whom he purchases such articles, to the effect that the same is not adulterated or misbranded within the meaning of this Act, designating it. Said guaranty, to afford protection, shall contain the name and address of the party or parties making the sale of such articles to such dealer, and in such case said party or parties shall be amenable to the prosecutions, fines, and other penalties which would attach, in due course, to the dealer under the provisions of this Act.

SEC. 10. That any article of food, drug, or liquor that is adulterated or misbranded within the meaning of this Act, and is being transported from one State, Territory, District, or insular possession to another for sale, or, having been transported, remains unloaded, unsold, or in original unbroken packages, or if it be sold or offered for sale in the District of Columbia or the Territories, or insular possessions of the United States, or if it be imported from a foreign country for sale, or if it is intended for export to a foreign country, shall be liable to be proceeded against in any district court of the United States within the district where the same is found, and seized for con-

fiscation by a process of libel for condemnation. And if such article is condemned as being adulterated or misbranded, or of a poisonous or deleterious character, within the meaning of this Act, the same shall be disposed of by destruction or sale, as the said court may direct, and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States, but such goods shall not be sold in any jurisdiction contrary to the provisions of this Act or the laws of that jurisdiction: *Provided, however*, That upon the payment of the costs of such libel proceedings and the execution and delivery of a good and sufficient bond to the effect that such articles shall not be sold or otherwise disposed of contrary to the provisions of this Act, or the laws of any State, Territory, District, or insular possession, the court may by order direct that such articles be delivered to the owner thereof. The proceedings of such libel cases shall conform, as near as may be, to the proceedings in admiralty, except that either party may demand trial by jury or any issue of fact joined in any such case, and all such proceedings shall be at the suit of and in the name of the United States.

SEC. 11. The Secretary of the Treasury shall deliver to the Secretary of Agriculture, upon his request from time to time, samples of foods and drugs which are being imported into the United States or offered for import, giving notice thereof to the owner or consignee, who may appear before the Secretary of Agriculture, and have the right to introduce testimony, and if it appear from the examination of such samples that any article of food or drug offered to be imported into the United States is adulterated or misbranded within the meaning of this Act, or is otherwise dangerous to the health of the people of the United States, or is of a kind forbidden entry into, or forbidden to be sold or restricted in sale in the country

in which it is made or from which it is exported, or is otherwise falsely labeled in any respect, the said article shall be refused admission, and the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any goods refused delivery which shall not be exported by the consignee within three months from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe: *Provided*, That the Secretary of the Treasury may deliver to the consignee such goods pending examination and decision in the matter on execution of a penal bond for the amount of the full invoice value of such goods, together with the duty thereon, and on refusal to return such goods for any cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shall forfeit the full amount of the bond: *And provided further*, That all charges for storage, cartage, and labor on goods which are refused admission or delivery shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future importation made by such owner or consignee.

SEC. 12. That the term "Territory" as used in this Act shall include the insular possessions of the United States. The word "person" as used in this Act shall be construed to import both the plural and the singular, as the case demands, and shall include corporations, companies, societies and associations. When construing and enforcing the provision of this Act, the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation, company, society, or association, within the scope of his employment or office, shall in every case be also deemed to be the act, omission, or failure of such

corporation, company, society, or association as well as that of the person.

SEC. 13. That this Act shall be in force and effect from and after the first day of January, nineteen hundred and seven.

Approved, June 30, 1906.

Public Law 75-717
75th Congress

[CHAPTER 675]

AN ACT

To prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

CHAPTER I—SHORT TITLE

SECTION 1. This Act may be cited as the Federal Food, Drug, and Cosmetic Act.

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

(a) The term "Territory" means any Territory or possession of the United States, including the District of Columbia and excluding the Canal Zone.

(b) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term "Department" means the Department of Agriculture of the United States.

(d) The term "Secretary" means the Secretary of Agriculture.

(e) The term "person" includes individual, partnership, corporation, and association.

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g) The term "drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories.

(h) The term "device" (except when used in paragraph (n) of this section and in sections 301 (i), 403 (f), 502 (c), and 602 (c)) means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term "official compendium" means the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any

article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

(o) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(p) The term "new drug" means—

(1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or mis-

branded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 404 or 505.

(e) The refusal to permit access to or copying of any record as required by section 703.

(f) The refusal to permit entry or inspection as authorized by section 704.

(g) The manufacture within any Territory of any food, drug, device, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 303 (c) (2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303 (c) (3), which guaranty or undertaking is false.

(i) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 404, 406 (b), 504, or 604.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 505, or 704 concerning any method or process which as a trade secret is entitled to protection.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done which such article is held for sale after shipment in interstate commerce and results in such article being misbranded.

(l) The using, on the labeling of any drug or in any advertising relating to such drug, of any representation or suggestion that an application with respect to such drug is effective under section 505, or that such drug complies with the provisions of such section.

INJUNCTION PROCEEDINGS

SEC. 302. (a) The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, and subject to the provisions of section 17 (relating to notice to opposite party) of the Act entitled "An Act to supplement existing laws against unlawful restraints and monopolies, and for other purposes", approved October 15, 1914, as amended (U. S. C., 1934 ed., title 28, sec. 381), to restrain violations of section 301, except paragraphs (e), (f), (h), (i), and (j).

(b) In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this Act, trial shall be by the court, or, upon demand of the accused, by a jury. Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 22 of such Act of October 15, 1914, as amended (U.S.C., 1934 ed., title 28, sec. 387).

PENALTIES

SEC. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 301, with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

(c) No person shall be subject to the penalties of subsection (a) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301 (a), that such article is not adulterated or misbranded, within the meaning of

this Act, designating this Act, or to the effect, in case of an alleged violation of section 301 (d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce; or (3) for having violated section 301 (a), where the violation exists because the article is adulterated by reason of containing a coal-tar color not from a batch certified in accordance with regulations promulgated by the Secretary under this Act, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the coal-tar color, to the effect that such color was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this Act.

SEIZURE

SEC. 304. (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce, or which may not, under the provisions of section 404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: *Provided, however,* That no libel for condemnation shall be instituted under this Act, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply (1) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this Act, or (2)

when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

(b) The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall confirm, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so

made within a reasonable time, the claimant may apply to the court of one such jurisdiction, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

(c) The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, his attorney or agent, to obtain a representative sample of the article seized, and as regards fresh fruits or fresh vegetables, a true copy of the analysis on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

(d) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this Act or the laws of the jurisdiction in which sold: *Provided,* That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this Act or the laws of any State or Territory in which sold, the

court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Act under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. Any article condemned by reason of its being an article which may not, under section 404 or 505, be introduced into interstate commerce, shall be disposed of by destruction.

(e) When a decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article.

(f) In the case of removal for trial of any case as provided by subsection (a) or (b)—

(1) The clerk of the court from which removal is made shall promptly transmit to the court in which the case is to be tried all records in the case necessary in order that such court may exercise jurisdiction.

(2) The court to which such case was removed shall have the powers and be subject to the duties, for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

HEARING BEFORE REPORT OF CRIMINAL VIOLATION

SEC. 305. Before any violation of this Act is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom

such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

REPORT OF MINOR VIOLATIONS

SEC. 306. Nothing in this Act shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this Act whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

PROCEEDINGS IN NAME OF UNITED STATES; PROVISION AS TO SUBPENAS

SEC. 307. All such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States. Notwithstanding the provisions of section 876 of the Revised Statutes, subpenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any such proceeding.

CHAPTER IV—FOOD

DEFINITIONS AND STANDARDS FOR FOOD

SEC. 401. Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: *Provided*, That no definition and standard of identity and no standard of quality shall be established for fresh

or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocadoes, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for avocadoes, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

ADULTERATED FOOD

SEC. 402. A food shall be deemed to be adulterated—

(a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared,

packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(b)(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406: *Provided*, That this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this Act and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this Act for the purposes of coloring citrus fruit.

(d) If it is confectionery, and it bears or contains any alcohol or nonnutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, natural gum, and pectin: *Provided*, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts,

or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.

MISBRANDED FOOD

SEC. 403. A food shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If it is offered for sale under the name of another food.

(c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(f) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) If it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 401, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 401, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

(i) If it is not subject to the provisions of paragraph (g) of this section unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each: *Provided*, That, to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in de-

ception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided*, That to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream.

EMERGENCY PERMIT CONTROL

SEC. 404. (a) Whenever the Secretary finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with micro-organisms during the manufacture, processing, or packaging thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he then, and in such case only, shall promulgate regulations providing for the issuance, to manufacturers, processors, or packers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing, or packing of such class of food, for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such regulations, and during

such temporary period, no person shall introduce or deliver for introduction into interstate commerce any such food manufactured, processed, or packed by any such manufacturer, processor, or packer unless such manufacturer, processor, or packer holds a permit issued by the Secretary as provided by such regulations.

(b) The Secretary is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of such permit, and the Secretary shall, immediately after prompt hearing and an inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

(c) Any officer or employee duly designated by the Secretary shall have access to any factory or establishment, the operator of which holds a permit from the Secretary, for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator.

REGULATIONS MAKING EXEMPTIONS

SEC. 405. The Secretary shall promulgate regulations exempting from any labeling requirements of this Act (1) small open containers of fresh fruits and fresh vegetables and (2) food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on con-

dition that such food is not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

TOLERANCES FOR POISONOUS INGREDIENTS IN FOOD AND CERTIFICATION OF COAL-TAR COLORS FOR FOOD

SEC. 406. (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 402(a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402 (a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents.

CHAPTER V—DRUGS AND DEVICES

ADULTERATED DRUGS AND DEVICES

SEC. 501. A drug or device shall be deemed to be adulterated—

(a)(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if it is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 504.

(b) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescrib-

ing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoepathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

(c) If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(d) If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

MISBRANDED DRUGS AND DEVICES

SEC. 502. A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight,

measure, or numerical count: *Provided,* That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha eucaine, barbituric acid, betaeucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethane; or any chemical derivative of such substance, which derivative has been by the Secretary, after investigation, found to be, and by regulations designated as, habit forming; unless its label bears the name, quantity, and percentage of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming".

(e) If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine,

Senate floor and in House hearings. 144 Cong. Rec. S5001 through *id.* at S6481 (daily eds. May 18 through June 17, 1998) (S. 1415, 105th Cong. (1988)) (the "McCain Bill," as modified and printed in the Cong. Rec., 144 Cong. Rec. at S. 5034-84 (daily ed. May 19, 1998)); *The Tobacco Settlement (Parts 1-3): Hearings Before the Subcomm. on Health and Environment of the House Comm. on Commerce*, 105th Cong. (1997-98). The President's 1999 State of the Union Address called for such legislation in the current Congress. 145 Cong. Rec. H260 (daily ed. Jan. 19, 1999). Thus, whether to grant FDA jurisdiction over tobacco products remains before Congress.[25] Since 1996, fifteen bills have been introduced to grant FDA such jurisdiction.[26] Each of these bills would have granted FDA jurisdiction either by creating a new

[25] The Government contends that the entire history of Congress' consideration and rejection of bills to give FDA jurisdiction over tobacco products is no more meaningful than Congress' inaction since FDA asserted jurisdiction. Pet. Br. at 42-43. To the contrary, Congress' "failure" to enact bills to overturn FDA's recent assertion of jurisdiction is easily understood given the immediate judicial challenge to that assertion, the district court's stay of FDA's regulations except for the youth access provisions, the subsequent appellate ruling and this Court's grant of certiorari. Moreover, in 1997, Congress expressly disavowed any intent to affect this case when it provided funding for those FDA regulations not stayed by the district court: "The [Senate] Committee [on Appropriations] is aware of the ongoing litigation. . . . *The Committee emphasizes that its action is in no way to be construed as concurring or disagreeing with any court ruling regarding FDA's authority . . . .*" S. Rep. No. 105-51, 105th Cong. 117 (1997) (emphasis added); see also S. Rep. No. 105-212, 105th Cong. 124 (1998) (same for FY '99); S. Rep. No. 106-80, 106th Cong. 127 (1999) (same for FY '00). Properly, the Government does not seek to draw any inference from the appropriation. *See TVA v. Hill*, 437 U.S. 153, 190 (1978).

[26] S. 527, S. 1414, S. 1415, S. 1492, H.R. 762, H.R. 1244, H.R. 3028 (all 105th Cong. (1997)); S. 1530, S. 1638, S. 1648, S. 1889, H.R. 3474, H.R. 3738, H.R. 3868, H.R. 3889 (all 105th Cong. (1998)).

regulatory scheme exclusively for tobacco products or by modifying the FDCA's standards for safety and effectiveness. *None* of these bills accepted FDA's view that the FDCA, as it stands, fits tobacco products. Rather, these bills reflect the Members' continued understanding that application of the FDCA to tobacco products would require a ban.

Congress has amended the FDCA 57 times in the past 60 years, but has never granted FDA jurisdiction over tobacco products.[27] If Congress had wanted to confer such jurisdiction on FDA, it would have said so by now. Even when interpreting a public health protection statute, as is the FDCA, "we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." *62 Cases . . . of Jam v. United States*, 340 U.S. 593, 600 (1951).

II. THE RELEVANT STATUTES AND THEIR HISTORY DEMONSTRATE THAT FDA LACKS JURISDICTION OVER TOBACCO PRODUCTS.

Both FDA's general assertion of authority and its tobacco regulations are incompatible with Congress' tobacco-specific legislation. The *only* way that the FDCA can be reconciled with the FCLAA, the CSTHEA, and the ADAMHA Amendments is to conclude that the FDCA does not cover tobacco products. In this context, statutes such as these should "be taken together, as if they were one law." *United States v. Stewart*, 311 U.S. 60, 64 (1940); *Hubbard v. United States*, 514 U.S. 695, 701 (1995). FDA's demand that this Court resolve this case exclusively on the basis of FDA's expansive reading of the definitions in the FDCA is, therefore, legally indefensible.

[27] *See* Walsh, Federal Food, Drug, and Cosmetic Act with Amendments iii-iv (amendments through 1980); 21 U.S.C. § 301 Historical & Statutory Notes 33-34 (West Supp. 1998) (amendments since 1980).

> The classic judicial task of reconciling many laws enacted over time, and getting them to "make sense" in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute.

United States v. Fausto, 484 U.S. 439, 453 (1988). Thus, the "proper inquiry is how best to harmonize", *United States v. Estate of Romani*, 118 S. Ct. 1478, 1486 (1998), the FDCA with the tobacco-specific legislation.

It is well settled that subsequently enacted and more specific statutes (like the tobacco-specific statutes) prevail over earlier and more general statutes (like the FDCA). Such later and more specific statutes preclude efforts to "extend the reach of the earlier Act's vague language to the limits which, read literally, the words might permit." *NLRB v. Drivers, Chauffeurs, Helpers, Local Union No. 639*, 362 U.S. 274, 291-92 (1960). Not only do "precisely targeted" statutes prevail over the more general when there are "numerous other regulations and statutes littering" the field, but a general statute should not be expanded "so dramatically as to make many other pieces misfits." *United States v. Sun-Diamond Growers of California*, 119 S. Ct. 1402, 1410 (1999).[28]

[28] The Government cites *TVA v. Hill*, 437 U.S. at 189-90, for the proposition that an "implied repeal occurs only when there is an irreconcilable conflict between the old and the new laws," and asserts that there is no "irreconcilable conflict" between Congress' tobacco-specific statutes "and the conclusion that tobacco products fall within the reach of the Act." Pet. Br. at 44. Respondents do not argue that any portion of the FDCA has been implicitly repealed by Congress' tobacco-specific statutes. Rather, the argument is that those statutes preclude FDA's novel construction of the FDCA. Thus, the standards for an implied repeal are irrelevant. *See Argentine Republic v. Amerada Hess Shipping Corp.*, 488 U.S. 428, 438 (1989) (rejecting implied repeal argument and noting that passage by Congress of a later statute precludes an expansive construction of an earlier statute). In any event, there *are* numerous irreconcilable conflicts between FDA's assertion of jurisdiction and Congress' tobacco-specific statutes.

The regulatory program established by Congress' tobacco-specific statutes, premised on the absence of FDA jurisdiction, reflects a political compromise that carefully balances economic interests, personal freedom, and principles of federalism with public health and other interests, including the need to reduce youth access to tobacco. This compromise marks the place where " 'opposing social and political forces have come to rest.' " *Chrysler Corp. v. Brown*, 441 U.S. 281, 313 (1979). FDA regulation of tobacco products is fundamentally at odds with Congress' program and would shatter that political balance.

A. FDA's Claim of Authority to Regulate Tobacco Products Is Incompatible with the Federal Cigarette Labeling and Advertising Act.

FDA's claim of authority over tobacco products cannot be reconciled with the policy and regulatory program Congress established in the FCLAA. In statutory text, the FCLAA announces:

> It is the policy of the Congress, and the purpose of this chapter, to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby—
>
> (1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and
>
> (2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and ad-

vertising regulations with respect to any relationship between smoking and health.

15 U.S.C. § 1331.

The Government improperly recharacterizes these purposes as simply seeking to avoid "diverse, nonuniform, and confusing cigarette labeling and advertising regulations." Pet. Br. at 45 (quoting FCLAA § 1331(2)(B)). This contention ignores the far broader purposes reflected in the other paragraphs of § 1331 and the operative provisions of the FCLAA. These include maintaining the primacy of Congress in establishing national policy with respect to smoking and health, and protecting commerce and the national economy consistent with the policy of informing consumers about the health risks associated with cigarettes. Congress' purpose to protect commerce while informing consumers, *codified at* § 1331(2)(A), necessarily precludes any federal agency from banning cigarettes.

Even FDA acknowledges that it lacks the statutory tools and the expertise to take account of these economic and political factors.[29] FDA is not authorized to protect "commerce and the national economy." Its role is limited to carrying out the mandate of its governing statute—a mandate that requires it to ban any drug or device not found to be both "safe" and "effective." *See* 21 U.S.C. §§ 355 (d)-(e), 360c(a)(2)(A)-(C), 360e(d)-(e). However, safety is one of several elements in Congress' complex political balance. Indeed, Congress determined in 1970 that cigarettes are "dangerous," Pub. L. No. 91-222, § 4, 84 Stat. 87 (1970), and accordingly, has prescribed specific warnings, 15 U.S.C. § 1333, but rejected a ban.

[29] "FDA medical officers should not be considering economic issues as part of their safety and efficacy reviews. . . . Although some people look to FDA to resolve those difficult dilemmas, FDA does not have the expertise to decide them." FDA Comm'r Kessler, *Remarks at the Symposium on Pharmacoeconomics* (Oct. 22, 1993).

The very grounds used by FDA to justify its attempt to regulate tobacco products without banning them—notwithstanding its finding that they are unsafe—show how far the Agency has overreached. FDA explains that the health care system could be "overwhelmed" by the need to treat addicted smokers if tobacco products were banned, and that in these circumstances "a black market and smuggling would develop to supply smokers." 61 Fed. Reg. 44,396, 44,413 (1996). But FDA has no expertise with respect to these issues—and no authority under the FDCA to consider them.[30]

Lacking suitable authority, FDA has sought to invent its own tobacco law to avoid a head-on collision with Congress' tobacco-specific statutes.[31] The court of appeals properly recognized this "transparent action by the FDA [as] obvious sophistry," taken "to attain its end, not the end contemplated by Congress." *Brown & Williamson*, Pet. App. at 24a, 30a. Notwithstanding FDA's inventions, a principled application of the FDCA would create numerous irreconcilable conflicts with the FCLAA:

[30] FDA's efforts to address "unique problems of medical judgment, law enforcement and public policy . . . cannot justify a federal agency of specifically delimited jurisdiction from implementing equally unique control solutions not authorized by Congress." *American Pharm. Ass'n v. Weinberger*, 377 F. Supp. 824, 831 (D.D.C. 1974), *aff'd sub nom. American Pharm. Ass'n v. Mathews*, 530 F.2d 1054 (D.C. Cir. 1976) (per curiam) (FDA's methadone distribution regulations "must be first passed upon by Congress").

[31] FDA's construction of the FDCA and the tobacco-specific statutes reads out of them their legislatively established "intelligible principle[s]," *J.W. Hampton Jr., & Co. v. United States*, 276 U.S. 394, 404-410 (1928) (Taft, C. J.): tobacco products are not immediately banned under the FDCA even though found "unsafe," nor regulated as Congress intended under the tobacco-specific statutes. FDA therefore would lack any congressional direction regarding how to regulate tobacco products. "A construction of the statute that avoids this kind of open-ended grant should certainly be favored." *Industrial Union Dep't, AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 646 (1979) (plurality opinion).

Authority to Ban. As the court of appeals recognized: "A faithful application of the statutory language would lead to a ban on tobacco products—a result not intended by Congress." *Id.* at 29a.[32] Under the FDCA, a drug or device is "misbranded" and may not be sold if it is "dangerous to health when used in the dosage or manner, . . . recommended, or suggested in the labeling thereof." 21 U.S.C. § 352(j). Yet FDA has found that cigarettes, when used in the recommended manner (*i.e.*, smoked), are "dangerous to health," 61 Fed. Reg. 44,396, 44,412 (1996), and are "the single leading cause of preventable death in the United States." *Id.* at 44,398. Thus, if the FDCA actually applied to tobacco products, they would have to be banned.[33]

---

[32] To bolster its argument that FDA may ban tobacco products, the Government conflates two issues: the preemptive effect of the FCLAA on state law; and the preclusive effect of the FCLAA on federal agencies. Pet. Br. at 45. But substantially different legal standards govern these separate issues, in part, due to the "strong presumption" against preemption, *Cipollone*, 505 U.S. at 523, "consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety." *Medtronic*, 518 U.S. at 485. *Cipollone* concerned the preemptive effect on state law of 15 U.S.C. § 1334. *Cipollone*, 505 U.S. at 517. Unlike *Cipollone*, this case involves the preclusive effect of the FCLAA on a federal agency; it cannot be decided by only reading § 1334.

[33] FDA's position is that tobacco products are "devices" that deliver the "drug" nicotine. But if FDA finds that there is a reasonable probability that a device will cause serious adverse health consequences, it "shall issue an order requiring the appropriate person . . . to immediately cease distribution of the device." 21 U.S.C. § 360h(e)(1). Moreover, any drug that is not "generally recognized" as safe may not be marketed unless FDA approves the drug as having been shown to be safe. 21 U.S.C. §§ 321(p), 355(b), 331(d). The Director of FDA's Center for Drug Evaluation and Research has noted that "for a drug that's going to be sold over-the-counter . . . there has to be a very high certainty that the drug is very safe." Woodcock, *When Is a Medical Product Too*

But banning tobacco products is manifestly inconsistent with Congress' intent. Congress has repeatedly refused to give FDA jurisdiction over tobacco products precisely *because* it would lead to a ban. Congress has never delegated that decision to any administrative agency—and certainly not to FDA, whose repeated denials of such authority were a predicate for Congress' own legislative program.

Labeling Authority. The FCLAA and the CSTHEA expressly preclude FDA or any other agency from requiring any statement on tobacco product labeling with respect to tobacco and health except as prescribed by Congress. 15 U.S.C. §§ 1334(a), 4406(a).[34] Yet regulation of product labeling is a core feature of FDA authority over "drugs" and "devices." *See generally*, 21 U.S.C. § 352. Indeed, the FDCA explicitly requires health warnings on drugs and devices. For example, a "drug" or "device" is "misbranded" if its labeling does not include "adequate warnings against use . . . by children where its use may be dangerous to health." 21 U.S.C. § 352(f)(2). Given that FDA called the use of tobacco products a "pediatric disease," 61 Fed. Reg. 44,396, 45,238 (1996), and concluded that tobacco products are "dangerous", *id.* at 44,412, FDA *must* require such warnings if tobacco products are "drugs" or "devices." But it is precluded from doing so by the FCLAA and the CSTHEA. To avoid the conflict without acknowledging it, FDA announced that the current congressionally-prescribed warn-

---

Risky? An Interview with FDA's Top Drug Official, FDA Consumer, The Magazine of the U.S. Food and Drug Administration, Sept.-Oct. 1999, at 10 ("FDA Consumer (Sept.-Oct. 1999)").

[34] Nothing in *Banzhaf v. FCC*, 405 F.2d 1082 (D.C. Cir. 1968), suggests the contrary. *Banzhaf* concerned regulation of broadcasters—not cigarette manufacturers—and did not require statements on tobacco product packages concerning smoking and health.

ings satisfy the FDCA. *Id.* at 44,465. But if FDA genuinely believed those warnings were truly "adequate," its regulations would be unnecessary.

Further, under the FDCA, a "drug" or "device" is misbranded unless its labeling contains "adequate directions" for safe use. 21 U.S.C. § 352(f)(1); 21 C.F.R. §§ 201.5, 801.5. Given FDA's findings, no such directions could possibly be written for tobacco products. But, even if such directions were possible, FDA could not require them consistent with the FCLAA because they would be in addition to the congressionally-prescribed warnings.

Finally, FDA's tobacco-product regulations would require all product packages to carry the health-based "intended use" statement: "Nicotine Delivery Device for Persons 18 or Older." 21 C.F.R. §§ 897.25, 897.32(c). To seek to avoid a conflict with the FCLAA and the CSTHEA labeling preclusions, FDA contends that this warning about nicotine is somehow unrelated to "smoking and health." 61 Fed. Reg. 44,396, 44,544 (1996). But the very basis of FDA's rulemaking is the health effects of nicotine "delivery" by tobacco products.

Package Inserts. FDA also claims authority to require that package inserts "contain health information and information about the chemicals added to cigarettes and smokeless tobacco." 61 Fed. Reg. 44,396, 44,465 (1996). FDA argues that the FCLAA does not preclude such package inserts because inserts would be "in"—not "on"—cigarette packages. *Id.* FDA was forced to adopt this absurd view of FCLAA preclusion given its desire to assert jurisdiction over tobacco products.

Ingredients. Congress determined that the health effects of cigarette ingredients are to be evaluated *by HHS* and reported *to Congress.* 15 U.S.C. § 1335a. Nevertheless, under FDA's regulation of tobacco products as "devices,"

FDA would evaluate—and sometimes could prescribe—their ingredients, *see* 21 U.S.C. §§ 360d(a)(2)(A), 360, 360e(c)(1)(B), thus usurping Congress' authority.

Moreover, the FCLAA mandates that cigarette manufacturers disclose to HHS the identity of all cigarette ingredients, which HHS must treat "as trade secret or confidential information," 15 U.S.C. § 1335a(b)(2)(A), and store "in a locked cabinet or file." *Id.* at § 1335a (b)(1)(C). By contrast, under the FDCA, a drug is misbranded unless its label includes "the established name and quantity . . . of each active ingredient" as well as "the established name of each inactive ingredient . . . ." 21 U.S.C. § 352(e)(1)(A)(ii, iii). In fact, FDA claims authority "to require labeling or listing of other substances present or delivered by cigarettes." 61 Fed. Reg. 44,396, 44,463 (1996). However, such requirement would result in the public disclosure of the very information that Congress protected from disclosure.

In sum, it is impossible to harmonize FDA's asserted authority over tobacco products with the regulatory program in the FCLAA. Rather, the court of appeals found that FDA has sought "to maneuver around the obstacles created by the operative provisions of the" FDCA, *Brown & Williamson,* Pet. App. at 29a; and "[c]ongressional policy . . . cannot be harmonized with the FDA's assertion of jurisdiction over tobacco products." *Id.* at 44a. This disharmony permits only one conclusion: Congress has not granted FDA such authority.

B. FDA's Assertion of Federal Control over Retail Sales Conflicts With Congress' Legislation to Foster and Support Restrictions on Youth Access to Tobacco Products at the State Level.

FDA's one-size-fits-all program conflicts with the purpose of the ADAMHA Amendments, which contemplate

varying approaches from one State to another. Indeed, the FDCA preempts the States from imposing "requirements" that are different from or in addition to FDA's. *See* 21 U.S.C. § 360k. Thus, if the FDCA applies to tobacco products, Section 360k would prohibit the States from establishing any youth-access restrictions and enforcement procedures that differ from FDA's regulations, even if those restrictions were specifically designed to fit local circumstances.[35] FDA's regulations would thus wrest the lead enforcement role from the States contrary to Congress' intent. 21 C.F.R. § 897.14. The regulations also transform every improper sale of a tobacco product by a local merchant into a federal offense, *see* 21 U.S.C. §§ 331(a), 333(f)(3); 21 C.F.R. § 897.1(b), expanding the scope of federal criminal jurisdiction without congressional authorization.

III. FDA MAY NOT SEIZE AUTHORITY OVER TOBACCO PRODUCTS FROM CONGRESS.

As the court of appeals observed: "At its core, this case is about who has the power to make this type of major policy decision." *Brown & Williamson*, Pet. App. at 53a.[36] Congress has repeatedly enacted tobacco-specific legislation to address the health risks associated with tobacco products—including those relied upon by FDA as the basis of its asserted jurisdiction. In so doing, Congress answered the "who" question, and established a policy *against* FDA jurisdiction. As the D.C. Circuit stated in *ASH v. Harris*, "[i]f the [FDCA] requires expansion [to cover cigarettes], that is the job of Congress." *ASH*, 635 F.2d at 243. The court of appeals agreed that "this type of decision involving countervailing national policy concerns is just the type of decision left for Congress." *Brown & Williamson*, Pet. App. at 22a.

As we have shown, Congress did not intend to grant FDA authority over tobacco products when it enacted the FDCA. For over 60 years, FDA denied that it had such authority until it reversed course in its 1995-1996 rulemaking.[37] FDA communicated its lack of jurisdiction to Congress repeatedly, forcefully and authoritatively—in testimony and official correspondence from senior Agency officials and their Cabinet-level superiors.

FDA's conduct was consistent with its statements. Immediately after the 1964 Surgeon General's Report, the FTC proposed a rule to require health warnings in cigarette advertising. *See* 29 Fed. Reg. 530 (1964). FDA did nothing. Nor did it respond to *any* of the Surgeon General's numerous subsequent reports on tobacco and health. It knew it had no jurisdiction. In such circumstances, both "established practice" and "the want of assertion of power by those who presumably would be alert to exercise it" are "significant in determining whether such power was actually conferred." *BankAmerica Corp. v. United States*, 462 U.S. 122, 131 (1983).

Congress understood and concurred with FDA's view that the FDCA does not extend to tobacco products. *See United States v. Rutherford*, 442 U.S. 544, 554 n.10 (1979) (legislative intent "correctly discerned" when Congress was aware of FDA interpretation and did not "alter

---

[35] FDA, in its discretion, may waive the FDCA preemption. But in triggering that authority, FDA has shifted primary authority from the States (and Congress) to itself.

[36] FDA recently recognized its inability to modify the fundamental policy underlying the FDCA: If there is "more that can be done" beyond "enforcing the standards and approach called for in our statute," to achieve a "*a balance [that is] correct according to society*," "[t]*hat's really a general consensus rather than our call.*" FDA Consumer (Sept.-Oct. 1999) at 11.

[37] Contrary to the Government's contention, FDA's prior position was not based on an absence of sufficient evidence regarding the "intended use" of tobacco products. Pet. Br. at 43. Rather, FDA asserted that, as a matter of law and congressional intent, it lacked authority over tobacco products absent health claims. *See, e.g.*, Novitch Letter, Jt. App. at 54, 67; *see also id.* at 47.

that interpretation although it . . . amended the statute").[38] Further, Congress repeatedly declined to pass legislation to grant FDA jurisdiction over tobacco products. "Congress' failure to act on the bills proposed on this subject provides added support for concluding that Congress acquiesced in the [agency's] rulings." *Bob Jones Univ. v. United States*, 461 U.S. 574, 601 (1983).

> [A] refusal by Congress to overrule an agency's construction of legislation is at least some evidence of the reasonableness of that construction, particularly where the administrative construction has been brought to Congress' attention through legislation specifically designed to supplant it.

United States v. Riverside Bayview Homes, Inc., 474 U.S. 121, 137 (1985).

The evidence of Congress' awareness of, and failure to overturn, FDA's longstanding interpretation, is far more compelling than the evidence in previous cases where this Court relied upon such facts. Here, the unenacted bills are unusually numerous (36) and span nearly 70 years (1929-1998), and thus reflect consistent congressional understanding of, and acquiescence in, the existing state of the law over a very long period.[39] Just last year, the

[38] The Government argues that *Motor Vehicle Mfrs. Ass'n v. State Farm*, 463 U.S. 29 (1983), precludes effective congressional ratification of FDA's longstanding statutory interpretation. Pet. Br. at 43. *State Farm*, however, involved an agency's policy judgment on a matter delegated to it to decide, not its interpretation of a statute. *State Farm* held only the former immune to congressional ratification, 463 U.S. at 45, not the latter.

[39] The Government notes that congressional will is expressed through enacted legislation, not unenacted bills. Pet. Br. at 42. Respondents agree. However, the purpose and meaning of the statutes Congress *did* enact, the FDCA, the FCLAA, the CSTHEA, and the ADAMHA Amendments, as well as Congress' intent in enacting those statutes, are brightly illuminated by the competing alternatives before Congress. In a further effort to avoid the force of this

Senate debated for three weeks the merits of comprehensive tobacco legislation, including extensive provisions which would have established FDA regulatory authority, and similar legislation was considered by the House Committee on Commerce.

Indeed, Congress' recognition that FDA lacks authority was a predicate for Congress' tobacco-specific legislation. Congress "believed that it was filling a regulatory void," *International Bhd. of Teamsters v. Daniel*, 439 U.S. 551, 570 (1979), when it created its tobacco-specific statutes, a belief which the FDA "actively encouraged." *Id.* The enactment of legislation that "implicitly recognizes" the construction of a statute is "persuasive of legislative recognition" that the "construction is the correct one." *Apex Hosiery Co. v. Leader*, 310 U.S. 469, 488-489 (1940); *see also United States v. American Trucking Ass'ns*, 310 U.S. 534, 550 (1940). Now that Congress has installed a statutory regime for tobacco, it is far too late for FDA to conjure up a contrary interpretation of its jurisdiction. *Cf. Morton v. Ruiz*, 415 U.S. 199, 237 (1974) ("too late now" for agency to change interpretation after it consistently "led Congress to believe that interpretation"); *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 289 (1974) (agency "not now free" to change its interpretation of statute).

Thus, Congress ratified FDA's prior construction of the FDCA when it enacted the FCLAA. In reserving to itself the authority to regulate tobacco products, and in constructing its own comprehensive regulatory scheme for

history, the Government asserts that "[c]ongressional inaction also 'lacks persuasive significance because several equally tenable inferences may be drawn from such action, including the inference that the existing legislation already incorporated the offered change.'" *Id.* The historical evidence here shows that any such inference is untenable: Congress plainly understood that FDA lacked authority to regulate tobacco products.

such products, Congress relied upon its own conclusion—buttressed by FDA's statements—that FDA lacked authority over tobacco products and would not take any action to negate or undermine Congress' specific enactments. Congress' tobacco-specific statutes therefore preclude FDA's new construction of the FDCA. *See CFTC v. Schor*, 478 U.S. 833, 846 (1986) (finding ratification "virtually conclusive" when "Congress has not just kept its silence by refusing to overturn the administrative construction, but has ratified it with positive legislation. . . ."); *see also* Eskridge, *Interpreting Legislative Inaction*, 87 Mich L. Rev. 67, 110-11 (1988) (finding the strongest case for presuming correctness of a prior agency statutory interpretation is a "building block interpretation," *i.e.*, "an authoritative settled interpretation . . . upon which public decisionmakers have (apparently) relied in developing further legal rules").

Simply put, FDA has appropriated Congress' constitutional authority to make major national policy. This Court has been especially skeptical of administrative interpretations that would forge new, major policies that must be resolved by Congress:

> Reviewing courts are not obliged to stand aside and rubberstamp . . . administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute. Such review is always properly within the judicial province, and the courts would abdicate their responsibility if they did not fully review such administrative decisions. . . . [Where the review is] of a judgment as to the proper balance to be struck between competing interests, "[t]he deference owed to an expert [agency] cannot be allowed to slip into a judicial inertia *which results in the unauthorized assumption by an agency of major policy decisions properly made by Congress.*"

NLRB v. Brown, 380 U.S. 278, 291-2 (1965) (quoting *American Ship Bldg. Co. v. NLRB*, 380 U.S. 300, 318 (1965)) (emphasis added); *see also BATF v. FLRA*, 464 U.S. 89, 97 (1983).

Here, "the thread between these regulations and any grant of authority by the Congress is so strained that it would do violence to established principles of separation of powers," *Chrysler Corp. v. Brown*, 441 U.S. at 307-308, to credit FDA's assertion of jurisdiction "with the 'binding effect of law.'" *Id.* at 308.

CONCLUSION

Accordingly, the Court should affirm the judgment of the court of appeals.

Respectfully submitted,

RICHARD A. MERRILL
HERBERT DYM
COVINGTON & BURLING
1201 Pennsylvania Ave., N.W.
Washington, D.C. 20004
(202) 662-6000
Counsel for Lorillard Tobacco Company

PETER T. GROSSI, JR.
Counsel of Record
ARNOLD & PORTER
555 12th Street, N.W.
Washington, D.C. 20004
(202) 942-5670
Counsel for Philip Morris Incorporated

ARTHUR N. LEVINE
DAVID S. EGGERT
JEFF RICHMAN
ERIC SUTER
ARNOLD & PORTER
555 12th Street, N.W.
Washington, D.C. 20004
Counsel for Philip Morris Incorporated